DEC 1 4 2012

5. 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The Assigned 510(k) number is k123010.

Submitter's Identification:

ACON Laboratories, Inc.

10125 Mesa Rim Road

San Diego, California 92121

Tel.: 858-875-8019
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Date Prepared: December 14, 2012

Contact Person:

Qiyi Xie
Senior Staff, Clinical & Regulatory Affairs

Proprietary Name of the Device:

On Call® Vivid Pro Blood Glucose Monitoring System

Common Name:

Glucose Test System

Classification Name:

Class II §862.1345 Glucose Test System

Predicate Device:

One Touch® Ultra® Blood Glucose Monitoring System
Lifescan, Inc., located at 1000 Gibraltar Dr., Milpitas, CA 95035, USA.
510(k) Number: K002134

Device Name: On Call® Vivid Pro Blood Glucose Monitoring System

Proprietary Name	Classification	Product Code	Description	Common Name
On Call® Vivid Pro Blood Glucose Monitoring System	862.1345 Class II	75 NBW	System, Test, Blood Glucose, Prescription	Glucose Test System
On Call® Vivid Pro Blood Glucose Meter and On Call® Vivid Pro Blood Glucose Test Strips	862.1345 Class II	75 CGA	Glucose Monitor	Glucose Meter & Test Strips
On Call® Vivid Pro Glucose Control Solution	862.1660 Class I	75 JJX	Single Analyte Control	Control Solution

Description:

The On Call® Vivid Pro Blood Glucose Monitoring System is a quantitative assay for the detection of glucose in capillary whole blood sampled from the fingertip. The glucose measurement is achieved by using the amperometric detection method.

The test strip has a reagent system including glucose oxidase and a mediator that reacts with glucose in the whole blood sample to produce an electrical current. This current is measured by the meter, and after calculation by the meter, the blood glucose concentration reading is displayed on the meter display, calibrated to a plasma reference.

The quality control of the On Call Vivid Pro Blood Glucose Monitoring System is performed by testing the test strip on meter with glucose control solution to confirm that the test strip and meter are working together properly. The glucose control solution contains a known concentration of glucose with preservatives in an aqueous based mixture. The control solution test result should fall within the predetermined control solution range for the given strip lot to confirm the accuracy of the On Call Vivid Pro Blood Glucose Monitoring System.

Intended Use:

The On Call® Vivid Pro Blood Glucose Monitoring System is an electrochemical enzymatic assay. It is used for the quantitative measurement of glucose in fresh capillary whole blood from the fingertip. The On Call® Vivid Pro Blood Glucose Monitoring System is intended for multiple patient use by health care professionals in health care facilities as an aid to monitoring the effectiveness of diabetes control programs. The system should only be used with single-use, auto-disabling lancing devices.

The On Call® Vivid Pro Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes mellitus, nor intended for use on neonates.

The On Call® Vivid Pro Blood Glucose Test Strips are used with the On Call Vivid Pro Blood Glucose Meter in the quantitative measurement of glucose in capillary blood from the finger.

The On Call® Vivid Pro Blood Glucose Control Solutions are for use with the On Call® Vivid Pro Blood Glucose Meter and Strips as a quality control check to verify the accuracy of blood glucose test results.

Technological Characteristics:

Specification of Blood Glucose Meter:

Feature	**Specification**
Measurement Range	20 to 600 mg/dL (1.1-33.3 mmol/L)
Result Calibration	Plasma-equivalent
Sample	Fresh capillary whole blood
Minimum Sample Size	0.8 µL
Test Time	5 seconds
Power Source	Two (2) CR 2032 3.0V coin cell batteries
Battery Life	Minimum of 1,000 measurements (without considering data transfer and test reminder alarms)
Glucose Units of Measure	The meter is pre-set at time of manufacturing to either millimoles per liter (mmol/L) or milligrams per deciliter (mg/dL) depending on the standard of your country. The meter will be set to mg/dL by default when sold in the United States.
Memory	Up to 500 records with time and date
Meter Size	3.58" x 2.28" x 0.83"
Display Size	1.58" x 1.42"
Weight	Approximately 60 g (without battery installed)
Operating Temperature	5-45°C (41-113°F)
Operating Relative Humidity	10-90% (non-condensing)
Hematocrit Range	20-70%
Data Port	9600 baud, 8 data bits, 1 stop bit, no parity

Comparison to Predicate Devices:

The On Call® Vivid Pro Blood Glucose Monitoring System is substantially equivalent to One Touch Ultra Blood Glucose Monitoring System, K002134.

Features	On Call® Vivid Pro Blood Glucose Monitoring System	One Touch Ultra Blood Glucose Monitoring System (K002134)
	Similarities	
Assay Method	Glucose oxidase biosensor	Same
Result Calibration	Plasma-equivalent	Same
Test Time	5 seconds	Same
Sample Type	Fresh capillary whole blood	Same
Glucose Units of Measure	mg/dL	Same
Operating Relative Humidity	10–90%	Same
Data Port	One Serial data port	Same
Measurement Range	20 to 600 mg/dL (1.1-33.3 mmol/L)	Same
Automatic Shutoff	Two minutes after last user action	Same
Battery Life	Minimum of **1,000** measurements (without considering data transfer and test reminder alarms)	1,000 tests
	Differences	
Minimum Sample Size	0.8 µL	1.0 µL
Hematocrit Range	20–70%	30–55%
Operating Temperature	5–45°C (41–113°F)	6–44°C (43–111°F)
Coding	Auto Coding by meter automatic recognition of the intended coding after strip insertion	Manual Coding by manually selecting code by pressing button
Meter Memory	Up to 500 records with time and date	150 blood glucose and control solution tests
Power Source	Two (2) CR 2032 3.0 V coin cell batteries	One (1) CR 2032 3.0V coin cell battery
Meter Size	3.53" x 2.28" x 0.85" (89.6mm x 58mm x 21.7mm)	3.12" x 2.25" x 0.85"
Meter Weight	Approx. 60 g (with battery installed)	1.5 ounces with battery (Approximately 42 g)

Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Guidance documents included the "FDA Guidance for Industry In Vitro Diagnostic Glucose Test System" and "FDA Guidance for Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems" as well as "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Compliance to applicable voluntary standards includes EN ISO 15197:2003 "In vitro diagnostic test systems – Requirements for in vitro whole blood glucose monitoring systems intended for use by patients for self testing in management of diabetes mellitus."

Laboratory Testing:

The performance characteristics of the On Call® Vivid Pro Blood Glucose Monitoring System were evaluated by performing the following studies: repeatability precision, intermediate precision, linearity, interfering agents, hematocrit effect, temperature effect evaluation – blood & control solution, low battery effect, altitude effect, sample volume, humidity effect, simulated shipping study – test strip & control solution, control value assignment, meter testing, software validation testing, electromagnetic compatibility and electrical safety testing as part of meter and strip validation testing.

Discussion of Clinical Tests Performed:

Clinical studies were conducted with lay persons and trained laboratory technicians using the On Call® Vivid Pro Blood Glucose Monitoring System. The study data were presented evaluating the system accuracy of the On Call® Vivid Pro Blood Glucose Monitoring System compared to the YSI Model 2300 STAT PLUS (K913806) per the ACON Clinical Study Protocol for the Blood Glucose Monitoring System. Study results indicate that nonprofessional, inexperienced lay persons were able to obtain comparable blood glucose readings when using the On Call® Vivid Pro Blood Glucose Monitoring System as compared to the results obtained by the trained technicians. In addition, the participating lay persons were questioned and responded as satisfied with the ease of operation by following the Instructions for Use in the User's Manual and the overall performance of the On Call® Vivid Pro Blood Glucose Monitoring System.

Conclusion:

The laboratory testing and clinical study results demonstrate that the On Call® Vivid Pro Blood Glucose Monitoring System is safe, effective and easy-to-use. It also demonstrates that the On Call® Vivid Pro Blood Glucose Monitoring System meets the accuracy requirements per EN ISO 15197 and as such is substantially equivalent to the One Touch Ultra Blood Glucose Monitoring System, currently sold on the U.S. market (K002134).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 14, 2012

ACON Laboratories, Inc.
c/o Qiyi Xie
10125 Mesa Rim Road
San Diego, CA 92121

Re: k123010
Trade/Device Name: On Call® Vivid Pro Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: CGA, NBW, JJX
Dated: September 26, 2012
Received: September 27, 2012

Dear Qiyi Xie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123010

Device Name: On Call® Vivid Pro Blood Glucose Monitoring System

Indications for Use:

The On Call® Vivid Pro Blood Glucose Monitoring System is an electrochemical enzymatic assay. It is used for the quantitative measurement of glucose in fresh capillary whole blood from the fingertip. The On Call® Vivid Pro Blood Glucose Monitoring System is intended for multiple patient use by health care professionals in health care facilities as an aid to monitoring the effectiveness of diabetes control programs. The system should only be used with single-use, auto-disabling lancing devices.

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Prescription Use ___x___ (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use ___x___ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) K123010